



SAINT LOUIS  
UNIVERSITY

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February 11, 2003

**Via E-Mail - SAPcomments@CDC.GOV**

Select Agent Program  
Centers for Disease Control and Prevention  
1600 Clifton Rd., E-79  
Atlanta, GA 30333

Re: Comments Seeking Clarification to Select Agent Program Regulations

Dear Sir or Madam:

Having reviewed the interim final rule promulgated by the Department of Health and Human Services, Office of Inspector General regarding the possession, use, and transfer of select agents and toxins, Saint Louis University (the "University") seeks clarification regarding the following specific regulatory requirements:

Section 73.0(a)(2). This section indicates that the safety and emergency response provisions contained in Section 73.13 are effective February 7, 2002. Reviewing Section 73.13, the University is unable to locate explicit reference to emergency response training requirements. Accordingly, the University seeks clarification as to the nature of the emergency response training obligations referenced in Section 73.0(a)(2).

Section 73.9. This section requires that an entity conducting activities regulated under Part 73 appoint a Responsible Official and that the Responsible Official be approved pursuant to Section 73.8 of the regulation. Section 73.8, when read in conjunction with Section 73.0(a)(4), requires that the entity submit a security risk assessment for the Responsible Official by April 12, 2003. The reason the University seeks clarification regarding these sections is that Section 73.7, when read in conjunction with Section 73.0(b)(1), indicates that the University must submit its registration application by March 12, 2003. Section 73.7(b)(2)(v) requires that this application include the name, and Attorney General identification number, for the University's Responsible Official. Accordingly, the regulation gives the University until April 12, 2003 to submit the name of its Responsible Official to the Attorney General, but requires that the University provide the name and identification number of the Responsible

Official as part of its application under Section 73.7 by March 12, 2003. As such, the University seeks clarification regarding the date by which it must submit information regarding its Responsible Official to the Attorney General.

Section 73.11(b)(7). This section indicates that the University must develop a security plan that, among other requirements, establishes a procedure for reporting and removing unauthorized persons. The University seeks clarification as to the meaning of the phrase “unauthorized persons” and the areas from which they must be removed.

Thank you for your assistance in clarifying the aforementioned issues. Please call if you have any questions regarding the requests or information contained herein.

Sincerely,

Martin M. Clay, Jr.